

K955846
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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

- 1. SUBMITTER'S NAME:** IVAC CORPORATION
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DATE PREPARED: December 22, 1995
- 2. DEVICE NAME:** Proprietary Name: Model 2082/2087 Temp Plus III Thermometers

Common Name: Electronic Thermometer

Classification Name: Clinical Electronic Thermometer
- 3. PREDICATE DEVICE:** IVAC Models 2080/2085 Temp Plus II Thermometers
Diatek SureTemp 4 Thermometer
- 4. DEVICE DESCRIPTION:** The IVAC Models 2082/2087 Thermometers are thermistor-based electronic thermometers that are used in clinical practice for measuring oral, rectal and axillary temperature. A thermistor located at the tip of the probe is placed in contact with tissue at the desired measurement site. A microprocessor measures resistance in the circuit and converts the resistance measurement to a temperature, which is then displayed.
- 5. INTENDED USE:** The intended use for the IVAC Models 2082/2087 Thermometers is to measure oral, rectal and axillary temperatures in clinical practice.
- 6. TECHNOLOGICAL CHARACTERISTICS:** The new IVAC Models 2082/2087 Thermometers use a new algorithm which allows the predictive mode to display a temperature in approximately ten seconds versus the current speed of thirty seconds. There are no other significant changes being made to the existing Models 2080/2085 Thermometers. NASA developed a microprocessor and electronics package employing novel predictive technology for accelerating the response time of slowly responding sensors. The hydrogen sensor system was modified to accept input from a medical type thermistor and was tested by NASA.

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**6. TECHNOLOGICAL
CHARACTERISTICS:**

The primary function of the modified thermometers are the same as the current IVAC Models 2080/2085 Thermometers and the Diatek SureTemp 4 Thermometer: to measure oral, rectal and axillary temperatures. The technological characteristics of the devices are the same and raise no new questions of safety and effectiveness. IVAC Corporation concludes that the new IVAC Models 2082/2087 Thermometers are substantially equivalent to the original IVAC Models 2080/2085 Thermometers and the Diatek SureTemp 4 Thermometers.